REMARKS

The final Office Action of June 4, 2002 has been received and carefully reviewed, and the foregoing amended claims and the following comments are a complete response thereto.

Claims 13 and 15-36 are all the pending claims for this application. By this Amendment, claims 13, 27 and 36 have been amended to recite that the lyophilizate "contains no polyethylene glycols or additional proteins". Since these features of the invention have been previously argued and/or considered by the Examiner, Applicants submit that these amendments do not raise any new issues requiring further search and/or consideration. No new matter has been added, and consideration and entry of the amended claims is requested.

I. Response to Rejection of Claims 13, 15-21 and 23-36 under 35 U.S.C. §102(e)

Claims 13, 15-21 and 23-36 are rejected under 35 U.S.C. §102(e) as being anticipated by Andya (USPN 6,267,958).

The Examiner has considered Applicants' arguments that Andya teaches away from the instant claims by requiring the presence of "polyethylene glycols and additional proteins" but does not view these arguments as being persuasive in view of the amended claims. The claims recite that the formulation is "essentially free" of these

components, which according to the Examiner, allows for their presence even if only in trace amounts. Furthermore, the Examiner does not consider Andya as necessarily requiring polyethylene glycols and additional proteins as lycoprotectants but they are each one kind of a lycoprotectant disclosed in the reference.

In view of the amended claims, Applicants submit that the Examiner's rejection has been obviated for the following reasons.

Claims 13 and 27 are directed to a lyophilizate and claim 36 is directed to a method of preparing the lyophilizate wherein the lyophilizate contains **no** polyethylene glycols or additional proteins.

The Examples in the present specification indicate that the described formulations appear to specifically exclude the use of polyethylene glycols and additional proteins. This along with the supporting disclosure found in the last paragraph on page 6 of the specification indicate the preferred exclusion of these components. Accordingly, Applicants have amended the claims to recite formulations that exclude polyethylene glycols and additional proteins.

The present claimed inventive composition and process and Andya's composition and process may fall within the general field of art for lyophilizates, but one skilled in the art would not have even considered the instant claimed composition and process as being disclosed by or inherent to the composition and process of Andya. Accordingly, claims 13, 15-21 and 23-36 are not anticipated by (nor obvious in view of) Andya and withdrawal of this §102(e) rejection is deemed proper.

II. Response to Rejection of Claims 13 and 15-36 under 35 U.S.C. §103(a)

Claims 13 and 15-36 are rejected under 35 U.S.C. §103(a) as being obvious over Andya in view of Michaelis (USPN 5,919,443).

The Examiner states that even if Michaelis teaches the disadvantages of high-molecular weight polymers, there is no specific teaching in Andya which necessitates the inclusion of polymeric auxiliary substances. The Examiner also states that the suggestion to combine the references was predicated on Michaelis' discovery that it is possible to produce stable forms of pharmaceutical agents with amino sugars as additives.

In view of the amended claims 13, 27 and 36, Applicants submit that the Examiner's rejection has been obviated for the following reasons.

Claims 13 and 27 are directed to a lyophilizate and claim 36 is directed to a method of preparing the lyophilizate wherein the lyophilizate contains **no** polyethylene glycols or additional proteins.

The Examples in the present specification indicate that the described formulations appear to specifically exclude the use of polyethylene glycols and additional proteins. This along with the supporting disclosure found in the last paragraph on page 6 of the specification indicate the preferred exclusion of these components. Accordingly, Applicants have amended the claims to recite formulations that exclude any and all traces of polyethylene glycols and additional proteins.

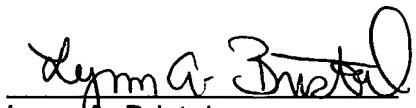
Applicants submit that the Examiner's rejection of the claims for *prima facia* obviousness fails for the reason that the combination of elements for the invention of Claims 13 and 15-36 are not disclosed by Andya or Michaelis alone or in combination.

CONCLUSION

In view of the foregoing amended claims and all of the foregoing arguments, Applicants submit that the Examiner's rejections of the claims under 35 U.S.C. §§102(e) and 103(a) are now overcome. That is, clear differences exist between the present invention as claimed and the prior art relied upon by the Examiner. These differences are more than sufficient that the present invention as claimed would not have been obvious to one of ordinary skill in the art at the time the invention was made viewing that prior art. Applicants submit that the claims as well as the entire application are now in condition for allowance, and the Examiner is requested to allow this application to pass to issuance.

The Commissioner is hereby authorized to charge any fee deficiency or credit any overpayment associated with this communication to Deposit Account No. 01-2300, referencing 108341-09011.

Respectfully submitted,



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Enclosure: Marked-Up Copy of Amended Claims
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MARKED-UP COPY OF AMENDED CLAIMS OF USAN 09/308,223

13. (Thrice Amended) A lyophilizate, comprising

[(1)] (a) a monoclonal antibody or a polyclonal antibody;

[(2)] (b) a sugar or an amino acid sugar;

[(3)] (c) at least one amino acid; and

[(4)] (d) a surfactant,

wherein the lyophilizate [is essentially free of] contains no polyethylene glycols [and] or additional proteins.

27. (Twice Amended) A lyophilizate, consisting essentially of

(a) a monoclonal antibody or a polyclonal antibody;

(b) a sugar or an amino acid sugar;

(c) at least one amino acid;

(d) a surfactant; and

(e) an inorganic acid as a buffering agent,

wherein the lyophilizate [is essentially free of] contains no polyethylene glycols [and] or additional proteins.

36. (Thrice Amended) A method of preparing a lyophilizate, the method comprising mixing a buffered solution containing a monoclonal antibody or a polyclonal antibody, a sugar or an amino acid sugar, at least one amino acid and a surfactant, to prepare a mixed solution, wherein the mixed solution has a pH value of 5-8; and

lyophilizing the mixed solution, wherein the lyophilizate [is essentially free of] contains no polyethylene glycols [and] or additional proteins.